

# Attachment II

Patent and Exclusivity Search Results from query on Appl No 019950 Product 001 in the OB\_Rx list.

## Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
019950	001	4404216	JAN 29,2004			
019950	001	4404216*PED	JUL 29,2004			

## Exclusivity Data

**There is no unexpired exclusivity for this product.**

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(c)(3)(5).
2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.
4. \*PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with \*PED as was done prior to August 18, 2003. Patents with \*PED added after August 18, 2003 will not contain any information relative to the patent itself other than the \*PED extension. Information related specifically to the patent will be conveyed on the original patent only.

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Orange Book Data Updated Through July, 2004

Orange Book Patent Data Only - **Daily**

Patent Data Last Updated: September 17, 2004



## Approved Active Moieties to which FDA has issued a Written Request for Pediatric Studies under Section 505A of the Federal Food, Drug, and Cosmetic Act

NOTE: This list simply identifies approved active moieties to which FDA has issued a Written Request for pediatric studies as of June 1998. If a product appears on this list, it does not imply that studies have been conducted or submitted to the Agency, nor does it mean that the studies described in the Written Request will be conducted. A sponsor is NOT required to perform pediatric studies in response to a Written Request. Conducting pediatric studies in response to a Written Request is voluntary. Upon occasion, information obtained by FDA subsequent to issuance of a Written Request causes FDA to rescind the Written Request. This list is not updated to indicate when a Written Request has been rescinded.

Total Approved Active Moieties Issued a Written Request = 253

Active Moiety	Sponsor
Abacavir	Glaxo Wellcome, Inc.
Acetazolamide	Wyeth-Ayerst
Adefovir	Gilead
Albuterol	Dey
Albuterol	GlaxoSmithKline
Alendronate	Merck
Almotriptan	Pharmacia & Upjohn
Alosetron	Glaxo Wellcome, Inc.
Alprazolam	Pharmacia & Upjohn
Amiodarone	Wyeth Ayerst
Amlexanox	Block Drug
Amlodipine	Pfizer, Inc.
Amlodipine/Benazepril	Novartis
Ammonium Lactate	Westwood Squibb
Amphetamine (mixed salts)	Shire
Amprenavir	Glaxo Wellcome, Inc.
Anagrelide	Shire
Anastrozole	Astra Zeneca
Argatroban	Texas Biotechnology

Aripiprazole	Otsuka
Atazanavir	Bristol-Myers Squibb
Atomoxetine	Lilly
Atorvastatin	Warner-Lambert
Atovaquone/Proguanil	Glaxo Wellcome, Inc.
Azelastine	ASTA Medica
Baclofen	Schwarz
Balsalazide	Salix Pharm.
Beclomethasone	Schering
Beclomethasone	3M
Benazepril	Novartis
Betamethasone	Schering
Betaxolol	Loxex Pharmaceuticals
Betaxolol	Alcon
Bicalutamide	AstraZeneca Pharm.
Bisoprolol	Wyeth-Ayerst
Brimonidine	Allergan, Inc.
Brinzolamide	Alcon
Budesonide	Astra Zeneca
Bupropion	Glaxo Wellcome, Inc
Buspirone	Bristol-Myers Squibb
Busulfan	Orphan Medical
C-Urea	Meretek
Calcitriol	Abbott
Candesartan	Astra Pharmaceuticals
Carboplatin	Bristol-Myers Squibb
Carteolol	CIBA
Carvedilol	SmithKline Beecham
Caspofungin	Merck

Celecoxib	Searle
Cerivastatin	Bayer
Cetirizine	Pfizer
Cilostazol	Otsuka
Cimetidine	SmithKline Beecham
Ciprofloxacin	Bayer
Ciprofloxacin	Alcon
Cisatracurium	Glaxo Wellcome
Citalopram	Forest Laboratories, Inc.
Clopidogrel	Sanofi-Synthelabo
Colesevelam	Sankyo Pharma
Cromolyn	Pharmacia & Upjohn
Cromolyn	Bausch & Lomb
Cytarabine	SkyePharma Inc.
Desflurane	Baxter Healthcare
Desloratadine	Schering
Dexrazoxane	Pfizer Pharm
Dichlorphenamide	Merck
Didanosine	Bristol-Myers Squibb
Dorzolamide	Merck
Efavirenz	DuPont Pharmaceuticals
Eletriptan	Pfizer, Inc.
Emtricitabine	Triangle Pharmaceuticals
Enalapril	Merck
Enfuvirtide (T-20)	Hoffman-La Roche
Enoxaparin	Aventis
Epirubicin	Pharmacia & Upjohn
Eplerenone	Searle
Ertapenem	Merck

Esmolol	Baxter Pharmaceutical
Esomeprazole	AstraZeneca
Etodolac	Wyeth-Ayerst
Famciclovir	Novartis
Famotidine	Merck
Felodipine	Astra Pharmaceuticals
Fenoldopam	Elan Pharmaceuticals
Fentanyl	Anesta
Fentanyl	Janssen Pharmaceutica
Fexofenadine	Aventis
Fluconazole	Pfizer
Fludarabine	Berlex
Fluocinolone	Bausch & Lomb
Fluoxetine	Lilly
Fluticasone	Glaxo Wellcome, Inc.
Fluvastatin	Novartis
Fluvoxamine	Solvay Pharmaceuticals
Formoterol	Novartis
Fosinopril	Bristol-Myers Squibb
Fosphenytoin	Pfizer
Fulvestrant	AstraZeneca Pharmaceut
Gabapentin	Parke-Davis
Gatifloxacin	Bristol-Myers Squibb
Gatifloxacin	Allergan
Gemcitabine	Lilly
Gemtuzumab	Wyeth-Ayerst
Gentamicin	Schering
Glatiramer	Teva
Glimepiride	Aventis Pharm.



## Approved Active Moieties to Which FDA has Granted Pediatric Exclusivity for Pediatric Studies under Section 505A of the Federal Food, Drug, and Cosmetic Act

NOTE: This list simply identifies approved active moieties with sponsors to which FDA has granted exclusivity for pediatric studies. Only applications held by the identified sponsor were granted pediatric exclusivity.

Total Exclusivity Determinations = 110

Total Approved Active Moieties Granted Exclusivity = 94

Total Approved Drugs Granted Exclusivity = 100

Active Moiety	Sponsor
Abacavir	Glaxo Wellcome, Inc.
Alendronate	Merck
Amlodipine	Pfizer
Ammonium lactate	Westwood-Squibb
Anagrelide	Shire
Atomoxetine	Lilly
Atorvastatin	Pfizer
Atovaquone/Proguanil	GlaxoSmithKline
Azelastine	Asta Medica
Benazepril	Novartis
Bisoprolol	Wyeth Ayerst
Brimonidine	Allergan
Budesonide	AstraZeneca

Buspirone	Bristol-Myers Squibb
Busulfan	Orphan Medical
Calcitriol	Abbott Laboratories
Carboplatin	Bristol-Myers Squibb
Cetirizine	Pfizer
Ciprofloxacin	Alcon
Ciprofloxacin	Bayer
Citalopram	Forest
Clofarabine	Ilex
Cromolyn	Pharmacia and Upjohn
Desloratadine	Schering
Didanosine	Bristol-Myers Squibb
Dorzolamide	Merck
Enalapril	Merck
Esmolol	Baxter
Etodolac	Wyeth Ayerst
Famotidine	Merck
Felodipine	Astra Zeneca
Fentanyl	Alza
Fexofenadine	Aventis
Fluconazole	Pfizer